UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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SERGEANTS BENEVOLENT ASSOCIATION HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated,

Plaintiff,

-against-

ACTAVIS, PLC, FOREST LABATORIES, LLC, MERZ PHARMACEUTICALS GMBH & CO., KGAA, AMNEAL PHARMACEUTICALS, LLC, TEVA PHARMACEUTICAL INDUSTRIES, INC., BARR PHARMACEUTICALS, INC., COBALT LABORATORIES, INC., UPSHER-SMITH LABORATORIES, INC., WOCKHARDT LIMITED, WOCKHARDT USA LLC, SUN INDIA PHARMACEUTICALS INDUTRIES, LTD., DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES, INC.,

Defendants.

x

No. 15-cv-6549 (CM)

JM SMITH CORPORATION d/b/a, SMITH DRUG COMPANY, individually and on behalf of all others similarly situated,

Plaintiffs,

-against-

ACTAVIS, PLC, FOREST LABATORIES, LLC, MERZ GMBH & CO. KGAA, MERZ PHARMACEUTICALS GMBH & CO. KGAA, and MERZ PHARMACEUTICALS GMBH

Defendants.

x

No. 15-cv-7488 (CM)

MEMORANDUM DECISION AND ORDER DENYING DEFENDANTS' MOTIONS TO DISMISS

McMahon, C.J.:

This action follows on the heels of a 2014 lawsuit brought by the State of New York against Defendant Actavis PLC and its wholly-owned subsidiary, Forest Laboratories, LLC (collectively, "Forest").[1] In that lawsuit, the State of New York alleged that Forest was attempting to force patients and physicians to switch from Namenda IR, a twice-daily drug that treats moderate-to-severe stages of Alzheimer's disease, to Namenda XR, a pharmacologically identical drug only taken once a day, by effectively removing Namenda IR from the market before its patent exclusivity period expired and a generic substitute to the Namenda drugs became available. By forcing consumers to make the switch, Forest could extend its monopoly over the leading treatment of moderate-to-severe stages of Alzheimer's disease and impede competition from generic manufacturers through the end of Namenda XR's patent exclusivity period in 2029. After finding that the State of New York had demonstrated a substantial likelihood of success on the merits, my colleague Judge Sweet issued a preliminary injunction barring Forest from restricting access to Namenda IR until Namenda IR's patent exclusivity period expired and generic versions of the drug entered the market. The Second Circuit upheld that ruling on appeal and Forest subsequently agreed to continue marketing Namenda IR.

Plaintiffs here are health plans that are direct and indirect purchasers of Namenda brand drugs. In complaints filed in three related cases, they allege that they have been forced to pay supracompetitive prices for their members' Alzheimer's disease treatments due to Forest's anticompetitive conduct. Like the State of New York, Plaintiffs allege that Forest violated federal and state antitrust laws by attempting to restrict access to Namenda IR, while adding

[1] Actavis, PLC, now known as Allergan PLC, acquired Forest Laboratories, LLC on July 1, 2014.

allegations that various generic companies also colluded with Forest to delay the entry of generic versions of Namenda IR by entering into settlements in which they agreed not to begin marketing generic Namenda IR until July 2015.

Before the Court are Defendants' motions to dismiss the complaints for failure to state a claim. For the reasons set forth below, the motions are denied as to Plaintiff J.M. Smith Corporation's federal claims. The corresponding state law claims asserted by Sergeants Benevolent Association Health & Welfare Fund are stayed pending resolution of the federal claims. The motions to dismiss those claims are denied without prejudice to renewal.

BACKGROUND

Opinions by Judge Sweet, *see New York v. Actavis, PLC*, No. 14 CIV. 7473, 2014 WL 7015198, at *1 (S.D.N.Y. Dec. 11, 2014) ("Namenda I"), and the Second Circuit Court of Appeals, *see Schneiderman ex rel. New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) ("Namenda II"), have described much of the background to this case. The facts and procedural history below, which are summarized only to the extent necessary to decide Defendants' motions to dismiss, borrow heavily from those decisions.

A. The Parties

Forest, a limited liability company incorporated in Delaware with offices in New York and New Jersey, manufactures and sells branded pharmaceutical products. In June 2000, Forest entered into a license and cooperation agreement with Defendants Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH (collectively with Defendant Merz GmbH & Co. KGaA, "Merz")[2], which gave Forest the exclusive right to market a memantine hydrochloride-based

[2] Merz is German company engaged in the development, production, and distribution of branded pharmaceutical products. (Complaint, *J.M. Smith Corp. v. Actavis, plc.*, No. 15-cv-7488 (S.D.N.Y. Oct. 13, 2015) (Dkt. No. 29) ("DPP Compl.") ¶ 21.)

("memantine") drug in the United States under U.S. Patent No. 5,061,703 (the "'703 Patent"). (DPP Compl. ¶¶ 2, 21, 93.) Pursuant to that agreement, Forest developed Namenda IR, a twice-daily immediate-release memantine drug, to treat moderate-to-severe stages of Alzheimer's disease. Namenda IR was approved by the Federal Food and Drug Administration ("FDA") in 2003 and launched in the United States in January 2004. *Namenda II*, 787 F.3d at 646. At the time, Namenda IR was the first medication in the United States approved for individuals suffering from moderate-to-severe stages of Alzheimer's disease and quickly became one of Forest's best selling drugs — generating approximately $1.5 billion in annual sales in 2012 and 2013. *Namenda II*, 787 F.3d at 647.

In June 2010, the FDA approved a second memantine drug developed by Forest: Namenda XR. Namenda XR is a once-daily extended-release drug. Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect; no studies have been done to show that Namenda XR is more effective than Namenda IR. *Id.* at 647; *Namenda I*, 2014 WL 7015198, at *19. Forest began marketing Namenda XR in 2013. *Namenda II*, 787 F.3d at 647

Defendants Barr Pharmaceuticals, Inc. ("Barr"),[3] Teva Pharmaceuticals, USA, Teva Pharmaceuticals Industries, Ltd. (collectively with Teva Pharmaceuticals, USA, "Teva"), Amneal Pharmaceuticals, LLC ("Amneal"), Cobalt Laboratories, Inc. ("Cobalt"), Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), Wockhardt Limited, Wockhardt USA LLC (collectively with Wockhardt Limited, "Wockhardt"), Sun Pharmaceuticals Industries, Ltd. ("Sun"), Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's," and collectively with Barr, Teva, Amneal, Cobalt,

[3] Barr Pharmaceuticals was previously known as Barr Laboratories. In 2008, it became a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. Complaint, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc.*, No. 15-cv-6549 (S.D.N.Y. Aug. 19, 2015) (Dkt. No. 1) ("IPP Compl.") ¶ 19.)

Upsher-Smith, Wockhardt, and Sun, "Generic Defendants") are actual, or were prospective, manufacturers of generic versions of Namenda IR. Between July 2009 and July 2010, the Generic Defendants all entered into separate licensing agreements with Forest in which they agreed to delay the launch of their generic versions of Namenda IR until July 11, 2015. (IPP Compl. ¶¶ 19-29.)

Plaintiff Sergeants Benevolent Association Health & Welfare Fund ("Indirect Purchaser Plaintiff") is a New York welfare fund that administers the prescription drug benefit plan of active and retired New York City Police Department sergeants and their dependents. (*Id.* ¶ 15.) As a third-party payer of pharmaceutical claims for members of the plan, it is an indirect purchaser of Namenda IR and alleges that during the class period, it indirectly purchased Namenda IR in eleven states at prices higher than it would have absent Defendants' unlawful anticompetitive conduct. (*Id.*)

J.M. Smith Corporation, d/b/a Smith Drug Company ("Direct Purchaser Plaintiff") is a South Carolina corporation that purchased Namenda IR directly from Forest and also alleges that during the class period, it paid prices higher than it would have absent Defendants' unlawful anticompetitive conduct. (DPP Compl. ¶ 18.)

B. The Hatch-Waxman Act

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, governs the manufacturing, selling, and marketing of pharmaceuticals in the United States. Under the FDCA, a pharmaceutical company must submit a New Drug Application ("NDA") to the FDA before it may bring a new drug to market. Because the NDA must provide the FDA with sufficient scientific data to demonstrate that the new drug is safe and effective, the approval process is often costly and time-consuming. *Namenda II*, 787 F.3d at 643; 21 U.S.C. § 355. Once

approved, though, a patented drug enjoys a period of exclusivity in the market. That period ends when the drug's patent expires and one or more low-cost generic versions of the drug enter the market and compete with the brand-name drug. *Namenda II*, 787 F.3d at 643. According to the FDA, generic versions of a drug, or "generics," are "copies of brand-name drugs and are the same as those brand-name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." FDA, Understanding Generic Drugs, http://1.usa.gov/1SjEIso (last visited July 27, 2016).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (the "Hatch–Waxman Act"), Pub. L. No. 98–417, 98 Stat. 1585, to serve the dual purposes of incentivizing innovation, by granting patent extensions to brand-name drug manufacturers, and lowering drug prices for consumers, by encouraging competition from generic drugs. *Namenda II*, 787 F.3d at 643-44. To encourage innovation, the Hatch–Waxman Act provides brand-name drug manufacturers new opportunities to extend their exclusivity period beyond the standard 20-year patent term. Under the Hatch-Waxman Act, brand-name drug manufacturers can extend their patents for up to five years as compensation for the time that lapsed during the FDA regulatory process, 35 U.S.C. § 156, and for an additional six-month period of "pediatric exclusivity" if the manufacturer conducts certain pediatric studies, 21 U.S.C. § 355a. *Namenda II*, 787 F.3d at 644.

To encourage competition, the Hatch-Waxman Act expedites the entry of generic drugs into the market once the patent exclusivity period on a brand-name drug expires. The Act allows the manufacturer of a generic version of an FDA-Approved drug to file an Abbreviated New Drug Application ("ANDA"), which allows the generic manufacturer to rely on the studies submitted by a brand-name drug manufacturer in connection with its NDA to show that the

generic is safe and effective. The FDA requires that a generic manufacturer certify in its ANDA application that a generic drug has the same active ingredients as, and is "bioequivalent" to, the already-approved brand drug. *Id.*; 21 U.S.C. § 355(j). A generic drug is bioequivalent to a brand drug if they two have the same "rate and extent of absorption" of an active ingredient — put differently, if they deliver the same amount of the same active ingredient over the same amount of time. *Namenda II*, 787 F.3d at 644; *see also* 21 U.S.C. § 355(j)(8)(B)(i). By allowing generic manufacturers to "piggy-back" on brand-name drug manufacturers' scientific studies, the Hatch-Waxman Act reduces the cost of FDA approval for manufacturers if low-cost generic drugs and speeds their introduction to market. *Namenda II*, 787 F.3d at 644.

C. Drug Substitution Laws And Product-Hopping

Generic competition is further encouraged by state drug substitution laws, which all 50 states and the District of Columbia have passed. *Namenda II*, 787 F.3d at 644. These laws either permit or require pharmacists to replace a prescribed brand-name drug with a therapeutically equivalent, lower-cost generic drug, absent an express indication from the prescribing physician that the prescription must be filled as written, provided that the generic drug has the same active ingredients, dosage form, and strength as the drug that was prescribed. *Id.* at 645; *see e.g.* N.Y. Educ. Law § 6816–a(1). Price competition at the pharmacy, facilitated by state generic substitution laws, is the principal means by which generics are able to compete in the United States. *Namenda I*, 2014 WL 7015198, at *27.

All drug substitution laws prohibit pharmacists from substituting generic drugs that are not "therapeutically equivalent" to a prescribed brand drug, though they differ in how they define "therapeutically equivalent." Thirty states adopted the FDA's definition of therapeutic equivalence and only allow a pharmacist to substitute a generic drug if the FDA designates the

generic as "AB-rated" in a publication known as the "Orange Book." *Namenda II*, 787 F.3d at 645. To receive an AB-rating, a generic must not only be bioequivalent but pharmaceutically equivalent to the brand drug, meaning that it has the same active ingredient, dosage form, strength, and route of administration as the brand drug. *Id.*

The AB-rated requirement, though intended to ensure therapeutic equivalence, provides brand-name drug manufacturers an opportunity to game the system through a practice called "product-hopping." *Namenda I*, 2014 WL 7015198, at *9. Before the patent on a brand-name drug expires and its manufacturer loses market share to generic competitors — what is referred to as going off the "patent-cliff" — the manufacturer develops a follow-on version of the drug with a later patent expiration date and encourages patients and their physicians to switch to that version. Because the generic version of the follow-on drug is not AB-rated to the original brand-name drug, pharmacies cannot substitute the generic version of the original drug for the follow-on version, even if, as is the case with Namenda IR and Namenda XR, the pharmacological difference between the original and the follow-on drug is negligible. *Id.*

Brand-name drug manufacturers use different tactics to encourage patients and physicians to switch to a follow-on drug. *Id.* at *10. A manufacturer may aggressively promote and market the new drug or reduce its price to encourage voluntary switching. This has been termed a "soft switch." A manufacturer may also stop selling the original version of the drug to force patients and physicians to switch to the follow-on drug. This has been termed a "hard switch." *Id.* at *17.

Brand-name drug manufacturers expect that once patients and physicians have switched to the follow-on product, through either a soft or hard switch, they will not switch back to the original product — a process referred to as "reverse commuting." *Namenda II*, 787 F.3d at 649. Reverse commuting tends to be especially low for people suffering from mid-to-late stages of

Alzheimer's disease; because they are highly vulnerable, the risk of changing a medical routine usually outweighs the benefit of changing to a lower cost drug. *Id.* at 656.

D. Generic Exclusivity

To further encourage manufacturers to market generic drugs, the Hatch-Waxman Act allows the FDA to grant a 180-day exclusive marketing period to the first generic manufacturer to file an ANDA. During this period, the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. (DPP Compl at ¶ 40; IPP Compl. at ¶¶ 52-53.)

Not all generic manufacturers qualify for the exclusivity period. When a generic manufacturer files an ANDA, it must assure the FDA that the generic it wishes to market will not infringe a brand-name manufacturer's patent. *F.T.C. v. Actavis, Inc.*, 133 S.Ct. 2223, 2228 (2013). The generic manufacturer can do so by making one of four certifications: (1) that the brand-name drug is not patented; (2) that the brand-name drug is patented but the patent has expired; (3) that the brand-name drug is patented, but the manufacturer will not market its product until after the patent expires; and (4) that the brand-name drug is patented, but that the patent is invalid or the generic will not infringe it. (DPP Compl. at ¶ 39; IPP Compl. at ¶¶ 40-41.) The final route is called a "Paragraph IV Certification." A generics manufacturer that is the first to file an ANDA but certifies FDA that it intends to wait until a brand-name drug's patents expires before marketing its product does not get a 180 day exclusivity period. (DPP Compl at ¶ 44; IPP Compl at ¶ 56.) Only a generics manufacturer that certifies that a brand-name drug's patent is invalid, or that its product does not infringe on the patent, receives the 180 day exclusivity period.

Because the 180 day exclusive marketing period can be extremely lucrative for generic manufacturers, *Actavis*, 133 S.Ct. at 2229, those manufacturers have a strong incentive to file an ANDA challenging the validity of a brand-name drug's patent early, even if the patent is ultimately found valid. (*See* DPP Compl at ¶ 44; IPP Compl ¶ 55.) The Hatch-Waxman Act controls for this problem by treating Paragraph IV Certification as an act of infringement and giving the holder of the brand-name drug patent the right to sue the prospective generic manufacturer immediately. (*Id.*) If a brand-name drug manufacturer does so within 45 days of being notified that a generic manufacturer filed a Paragraph IV Certification, the FDA will delay approval of the ANDA for 30 months, unless a court decides first that the patent is invalid or not infringed by the generic manufacturer's product, in which case the FDA will follow that determination. (DPP Compl at ¶ 40; IPP Compl ¶¶ 40-41.) *See* 21 U.S.C. § 355(j)(5)(B)(iii). If a court does not decide that the patent is invalid or not infringed by the generic manufacturer's product within the 30 month period, the FDA may give the generic approval to market the generic product. *Actavis*, 133 S.Ct. at 2228. Once it receives FDA approval, the generic manufacturer may begin selling its product, though if it does so before a court rules in its favor, it risks having to pay the brand-name manufacturer damages for patent infringement.

E. Generic Settlements

In the fall of 2007, fourteen or more generics manufacturers — including each of the Generic Defendants — filed ANDAs with the FDA seeking to market AB-rated generic versions of Namenda IR, whose patent was set to expire in October 2015. (DPP ¶¶ 102-03; IPP ¶¶ 68.) Each of these manufacturers certified that the Namenda IR patent was invalid or not infringed by their drugs. (IPP Compl. ¶ 69.) Forest responded by filing patent infringement lawsuits against

each of the generic manufacturers, which triggered the Hatch-Waxmen Act's 30 month stay on FDA final approval. (IPP Compl. ¶¶ 70-71.)

Forest chose to settle the patent lawsuits filed against each of the Generic Defendants instead of litigating the cases. (IPP Compl. ¶ 75.) Pursuant to these settlement agreement, which were signed between July 2009 and July 2010, Forest and the Generic Defendants entered into licensing agreements allowing the Generic Defendants to launch generic versions of Namenda IR, but not until July 11, 2015.[4] (IPP Compl. ¶ 76.) July 11, 2015 was months before Namenda IR's patent expired, but well after the Generics Defendants could have begun selling generic Namenda IR if Forest's patent was found to be invalid.

Between January and April 2010, the FDA tentatively approved several ANDAs, including those filed by the Generic Defendants, signaling that they would receive final approval after the end of the 30 month stay. In April and May 2010, Generic Defendants Dr. Reddy's and Sun received final approval for generic versions of Namenda IR; Teva and Orchid received final approval in October 2011 and March 2012 respectively.

F. The Preliminary Injunction

Forest brought Namenda XR to market in July 2013 — three years after it was approved by the FDA and two years before Namenda IR's patent exclusivity period expired. Because Namenda XR has a different strength and dosage than Namenda IR, generic Namenda IR drugs are not therapeutically equivalent under FDA regulations and cannot be substituted for Namenda XR under most, if not all, state drug substitution laws. *Namenda* II, 787 F.3d at 647.

To take advantage of this fact, Forest employed several "soft switch" tactics to encourage patients and physicians to switch from Namenda IR to Namenda XR and to avoid the patent cliff.

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[4] By July 2009, Barr had become a subsidiary of Teva. (IPP Compl. ¶ 76.)

Id. For instance, Forest stopped actively marketing Namenda IR and began heavily promoting Namenda XR to patients and physicians. Forest also sold Namenda XR at a discounted rate and issued rebates to health plans to make Namenda XR considerably less expensive than Namenda IR for health providers and patients. *Id.*

In early 2014, Forest decided that these efforts were not going to be successful alone; internal projections estimated that only 30% of Namenda IR consumers would switch to Namenda XR before the drug's patent expired. *Id.* In an effort to capture a larger percentage of Namenda IR users, Forest announced on February 14, 2014 that it would effectively discontinue Namenda IR. Forest notified the FDA of its plans, published letters on its websites urging caregivers and healthcare providers to "discuss switching to Namenda XR" with their patients, and requested that Namenda IR be removed from the Centers for Medicare & Medicaid Services' formulary list, in hopes of discouraging Medicare health plans from covering it. After a delay caused by a disruption in Namenda XR production, Forest announced in June 2014 that Namenda IR would be unavailable beginning Fall 2014 for all but a small segment of users for whom a doctor had stated that Namenda IR was "medically necessary." *Id.*

On February 28, 2014 — shortly after Forest had announced its intention to discontinue Namenda IR — the Antitrust Bureau of the Office of the Attorney General of the State of New York opened an investigation into Forest's plans regarding Namenda IR. *Namenda I*, 2014 WL 7015198, at *2. On September 15 2014, the State of New York filed a complaint alleging that Forest's decision to restrict access to Namenda IR was intended to maintain their monopoly in the memantine-drug market by thwarting competition from generics in violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, as well as New York's Donnelly Act, N.Y. Gen. Bus. Law § 340, et seq. *Id.*; *see also Namenda II*, 787 F.3d at 649. The State sought a preliminary injunction

barring Forest from restricting access to Namenda IR during the course of the litigation. *Namenda II*, 787 F.3d at 649.

After a five day-hearing on the State's preliminary-injunction motion — a hearing in which it received testimony from 24 witnesses and reviewed over 1,400 exhibits — Judge Sweet made several key findings, including that once-daily Namenda XR and the twice-daily Namenda IR were the only memantine therapies available to Alzheimer's patients prior to generic entry; that as a result, Forest's withdrawal of Namenda IR from the market prior to generic entry would force Alzheimer's patients that are currently dependent on memantine therapy to switch to Namenda XR; that if Defendants forced these Alzheimer's patients to switch to Namenda XR prior to generic entry, those patients would be unlikely to switch back to Namenda IR, even after generic versions of Namenda IR became available; that the generic versions of Namenda IR that were poised to enter the market in July and October 2015 would not be AB-rated to Namenda XR, because the generics and Namenda XR have different strengths and dosages; and that not being AB-rated to Namenda XR was likely to prevent generic Namenda IR drugs from competing with Namenda XR under state drug substitution laws and would likely thwart competition in the memantine-drug market. *Id.* at 649. Significantly, the court also concluded that the Forest's explicit purpose in withdrawing Namenda IR from the market was to impede generic competition and to avoid the patent cliff. *Id.*

Based on those findings, Judge Sweet granted New York's request for a preliminary injunction. According to the court, the state had raised serious questions regarding the merits of its claims under the Sherman and Donnelly Acts, demonstrated the potential for irreparable harm, and concluded that the equities favored an injunction. *Id.* The injunction required Forest to "continue to make Namenda IR (immediate-release) tablets available on the same terms and

conditions applicable since July 21, 2013" during the term of the injunction ("Injunction Term"), to "inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction . . . and the continued availability of Namenda IR," and to not "impose a 'medical necessity' requirement or form for the filling of prescriptions of Namenda IR during the Injunction Term." *Id.* at 649-50. The Injunction Term was from the date of its issuance — December 15, 2014 — through July 11, 2015 — the date when generic memantine was first to become available. *Id.* at 649-650.

The Second Circuit affirmed the district court's ruling on appeal. Significantly, for purposes of this motion, it also characterized the "hard switch" as follows:

> The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a "standstill" during the litigation proceedings described below. Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.

Namenda II, 787 F.3d at 648. According to the Second Circuit, the hard switch was not just the act of removing Namenda IR from the market; rather, it was the entire strategy of forcing consumers to switch to Namenda XR by removing Namenda IR from the market.

After the Second Circuit issued its decision, Forest agreed to leave Namenda IR on the market through July 2015. Following generic entry, the price of generic Namenda IR fell to less than 10% of the price of Namenda IR in July 2015. (DPP Compl. ¶ 118 n.2.)

G. Procedural History

Following the Second Circuit's May 2015 decision, several class action lawsuits were filed against Forest and the Generic Defendants in federal court. On August 19, 2015, the Indirect Purchaser Plaintiff filed its first complaint, which was assigned to this Court after being deemed related to a matter — voluntarily dismissed soon thereafter — on this Court's docket.

(*See* Case No. 15-cv-06549, Dkt. No. 2.)[5] The Indirect Purchaser Plaintiff alleged that Forest engaged in a two-part scheme to block generic competition to Namenda IR: (1) it conspired with at least a dozen generic manufactures of AB-rated generic versions of Namenda IR to drop their challenges to Forest and Merz's '703 Patent and agreed to delay the launch of their products until after its expiration; and (2) it sought to force consumers of Namenda IR to switch to Namenda XR before market entry of generic Namenda IR. (IPP Compl. ¶ 4.) The complaint brought claims against Forest for monopolization (Count I), against Forest and the Generics Defendants for conspiracy to monopolize (Count II), against Forest and the Generics Defendants for unfair and deceptive trade practices (Count III), and against Forest and the Generics Defendants for unjust enrichment (Count IV), all under a litany of state laws. (IPP Compl. at ¶¶ 191-231.) No federal claims were alleged.

On September 22, 2015, the Direct Purchaser Plaintiff filed a complaint against Forest and the Merz Defendants on substantially the same grounds. The Direct Purchaser Plaintiffs asserted a claim against Forest for the unlawful maintenance of monopoly power under Section 2 of the Sherman Act for forcing Namenda IR consumers to switch to Namenda XR (Count I); a claim against Forest for the unlawful maintenance of monopoly power under Section 2 of the Sherman Act "through an overarching scheme to prevent of delay generic competition" (Count II); a claim against Forest for the unlawful maintenance of monopoly power under Section 2 of the Sherman Act for entering into agreements with generic manufactures to delay generic entry

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[5] On February 12, 2016, the Indirect Purchaser Plaintiff filed a First Amended Complaint naming the correct Merz entities as defendants, but making no other substantive changes. (*See* Case No. 15-cv-06549, Dkt. No. 92.) The Indirect Purchaser Plaintiff notified the Court that the previously filed motions to dismiss would apply to the First Amended Complaint. (*Id.*) After accepting service of the First Amended Complaint, the Merz Defendants joined Forest's motion to dismiss the Indirect Purchaser Plaintiff's complaint and incorporated Forest's memorandum of law and reply in support of its motion by reference. (*See* Case No. 15-cv-06549, Dkt. No. 97.)

for three months past the expiration of the '703 patent (Count III); and two sets of claims against Forest and Merz for restraint of trade under Section 1 of the Sherman Act for entering into agreements with potential generic manufactures to delay their entry into the market for three months beyond the expiration of the '703 patent term (Counts VI and V). (DPP Compl. at ¶¶ 237-274.) No state claims were alleged.

The complaint was deemed related to the Indirect Purchaser Plaintiff's complaint and assigned to this Court's docket. (*See* Case No. 15-cv-7488, Dkt. No. 2.)

A third complaint against Forest and the Merz Defendants was filed by a second direct purchaser of Namenda IR. (*See* 15-cv-10083, Dkt. No. 1.) The parties stipulated that the two cases brought by direct purchasers should be consolidated, with the complaint filed by the Direct Purchaser Plaintiff being deemed the operative complaint. (*See* 15-cv-7488, Dkt. No. 65.)

On December 8, 2015, the parties moved the Court for leave to file consolidating briefing with respect to the complaints filed by the Indirect Purchaser Plaintiff and Direct Purchaser Plaintiff. (*See* Case No. 15-cv-06549, Dkt. No. 63.) On December 9, 2015, the Court granted the parties' request, ordering Forest and the Generic Defendants to each file a single memoranda of law in support of their motions to dismiss the two complaints; the Indirect Purchaser Plaintiff to file two memoranda of law in opposition to Defendants' motions to dismiss their complaint, one in opposition to Forest's motion and one in opposition to the Generic Defendants' motion; and the Direct Purchaser Plaintiff to file a single memorandum of law in opposition to Defendants' motions to dismiss. (*See* Case No. 15-cv-06549, Dkt. No. 64.)

Forest and the Generic Defendants filed their motions to dismiss soon thereafter. (*See* Case No. 15-cv-06549, Dkt. Nos. 80, 83.) In brief, Forest and the Merz Defendants argue that Plaintiffs did not state a federal claim for product hopping, because Judge Sweet's injunction

prevented the hard switch or any alleged exclusionary conduct from occurring; Forest's settlement agreements with generic manufactures were not illegal, since they did not contain any anticompetitive reverse payments; Plaintiffs failed to allege an overarching conspiracy or scheme; and the Direct Purchaser Plaintiff's claims were time-barred by the applicable statute of limitations. (*See id.*) The Generic Defendants argue, on the largely the same grounds, that the settlement agreements did not contain actionable reverse payments, that the Indirect Purchaser Plaintiff had not alleged an overarching conspiracy, and that the Indirect Purchaser Plaintiff failed to plead an antitrust injury.

Both sets of Defendants also addressed Plaintiffs' state law claims. Those arguments are not addressed in this opinion.

DISCUSSION

I. Standard For Motion to Dismiss

No heightened pleading requirements apply in antitrust cases. *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001). Thus, a motion to dismiss antitrust claims is governed by the familiar standard of Rule 12(b)(6). In deciding a motion to dismiss under Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007).

However, to survive a motion to dismiss, "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed

factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations, citations, and alterations omitted). Thus, unless a plaintiff's well-pleaded allegations have "nudged [her] claims across the line from conceivable to plausible, [the] complaint must be dismissed." *Id.* at 570; *Iqbal*, 556 U.S. at 680.

II. Plaintiffs Have Stated a Monopolization Claim for Product Hopping

Forest first argues that Plaintiffs' state and federal product-hopping claims must be dismissed because Plaintiffs cannot plausibly allege either anticompetitive conduct or standing. According to Forest, Judge Sweet's preliminary injunction required Forest to continue making Namenda IR tablets available past July 11, 2015, the day generic versions of the drug became available. Defendants argue that because Forest was not able to follow-through with its planned "hard-switch," Plaintiffs cannot show that Forest engaged in any anticompetitive conduct that would have had a substantially adverse impact on competition in the memantine-drug market or caused Plaintiffs to suffer damages. (Mem. ISO Defs. Forest and Merz's Mot. to Dismiss Indirect Purchaser Pls.' Class Action Compl. and Direct Purchaser Pls.' First Am. Class Action Compl. (Dkt. 85) ("Forest Br.") at 17-27.) Defendants contend that Defendants have, at most, pleaded a soft switch, which is not a violation of the federal antitrust laws.

In response, Plaintiffs contend that Forest's motion overlooks the fact that its anticompetitive "hard switch" began well before the district court entered its injunction and that Plaintiffs suffered damages as a result of this pre-injunction conduct. According to Plaintiffs, patients began switching to Namenda XR as soon as Forest announced that it would withdraw Namenda IR from the market. (Direct Purchaser Pls.' Mem. in Opp'n to Defs. Forest and Merz' Mot. to Dismiss Indirect Purchaser Pls.' Class Action Compl. and Direct Purchaser Pls.' First

Am. Class Action Compl. (Dkt. No. 69) ("DPP's Forest Br.") at 30-35; End Payor Pl.'s Opp'n to Defs. Forest's and Merz's Mot. to Dismiss (Dkt. No. 87) ("IPP's Forest Br.") at 22-23.) Though Judge Sweet's injunction blunted much of the success of Forest's "hard switch," in that fewer Namenda IR patients ultimately moved to Namenda XR, Forest's anticompetitive tactics between February 14, 2014 and December 11, 2014 caused some number of consumers to switch medications in anticipation of Namenda IR's withdrawal. (DPP's Forest Br. at 32-34; IPP's Forest Br. at 22-23.)

This issue has an easy resolution: Plaintiffs' argument is wholly supported by the *Namenda* decisions, and so Plaintiffs' argument is plausible on its face.

As Plaintiffs argue, Judge Sweet's findings of facts state that Forest's anticompetitive conduct began well before the proposed withdrawal was scheduled to take place. Judge Sweet found that on February 14, 2014 — eight months after Forest first considered alternatives to the soft switch and one month after it announced its decision to withdraw Namenda IR on an earnings call with investors — "Forest began the 'forced switch' by publicly announcing that Namenda IR tablets would be discontinued on August 15, 2014." *Namenda I*, 2014 WL 7015198, at *18. That same day, Forest notified the FDA that it intended to discontinue the sale of Namenda IR tablets and published open letters to physicians and caregivers on its website announcing its plan and urging caregivers to "speak with their loved ones' healthcare providers as soon as possible to discuss switching to Namenda XR." *Id.* (internal quotations omitted).

These efforts likely had the intended effect of encouraging Namenda IR patients to switch to Namenda XR — well before the proposed withdrawal was schedule to take place. According to Judge Sweet, 50% of existing Namenda IR patients had already converted to Namenda XR by the hearing on the preliminary injunction. *Id.* at 29. Many of those switches

surely resulted from the Company's soft-switch campaign; Forest not only marketed the new drug heavily, but also reduced the price to make it cheaper than Namenda IR. However, Judge Sweet found that, as Forest surely hoped, "physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR" and, in the words of one witness at the preliminary hearing, viewed it as forcing a "wholesale switch" from Namenda IR to Namenda. *Id.* at 18. Given this finding, it is entirely plausible that physicians and their patients preemptively switched medications and had already started using Namenda XR by the time the injunction was entered. Indeed, Forest's internal estimates themselves indicate that the hard switch campaign had proved successful by the date of the preliminary hearing; the percentage of Namenda IR patients that the Company estimated would switch to Namenda XR due to the soft switch campaign by July 2015 alone — 30% — had already been far exceeded by the hearing on the preliminary injunction in November 2014. *See id.* at 28.

Given these findings, Plaintiffs' allegations are more than sufficient to state a claim that is plausible on its face. Because Alzheimer's patients that switch medications infrequently "reverse commute," it is plausible that Plaintiffs continued to pay for Namenda XR prescriptions *after generic entry* for each of its members that switched to Namenda IR before the injunction was entered. Had these members not switched to Namenda XR, pharmacists would have begun filling their Namenda IR prescriptions with a generic version when one became available in July 2015. This would have, effectively, reduced the cost to Plaintiffs of treating these members by approximately 90% (or slightly less if Forest continued to market Namenda XR below the price of Namenda IR). If any of these members that switched to Namenda XR prior to the entry of the injunction did so *because* of Namenda's hard switch — which, again, is certainly plausible,

given Judge Sweet's finding that physicians interpreted Forest's announcement as a warning to switch medications — then Plaintiffs suffered damages due to Forest's illegal conduct.

To be sure, the Court needs to tread carefully when relying on Judge Sweet's opinion, since he never concluded that Forest broke the law. But that fact does not justify granting Defendants' motions to dismiss. Plaintiffs' claims are still plausible based on what Judge Sweet said the State of New York was *substantially likely* to show at trial. Similarly, the fact that Judge Sweet did not distinguish between conduct that had already occurred by the date of the hearing and actions that Forest planned to take in the future does not warrant dismissal of Plaintiffs' claims. Plaintiffs need only plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *See Iqbal*, 556 U.S. at 678. Plaintiffs have clearly done so here.

Defendants argue — mistakenly — that Plaintiffs' claims have to be dismissed nonetheless. First, they contend that Plaintiffs' theory is either foreclosed or at least not supported by the Second Circuit's decision affirming Judge Sweet's order granting the injunction. (*See, e.g.,* Forest's Br. at 19.) According to Defendants, Forest's conduct prior to the injunction (and before Namenda IR was withdrawn) was a lawful attempt to convince Namenda IR patients to switch to Namenda XR while Namenda IR remained on the market, and this conduct was "specifically allowed" by the Second Circuit's decision, which stated, "As long as [Forest] sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) . . . patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive conduct." (*Id.*) *See Namenda II*, 787 F.3d at 648.

Unfortunately for them, Defendants' characterization of their pre-injunction conduct and their reading of the Second Circuit's decision are entirely unsupportable — as the full passage they quote makes clear. According to the Second Circuit:

> Defendants' hard switch crosses the line from persuasion to coercion and is anticompetitive. As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives. By effectively withdrawing Namenda IR prior to generic entry, Defendants forced patients to switch from Namenda IR to XR — the only other memantine drug on the market.

Namenda II, 787 F.3d at 648.

The Second Circuit decision does not at all immunize Defendants' conduct prior to the entry of the injunction by saying that all of Forest's conduct before it was scheduled to withdraw Namenda IR was competition on the merits. Rather, all the Second Circuit held was that Forest's hard switch strategy — whether it began before or after the entry of the injunction — was illegal because it sought to deprive consumers of the choice between once-daily Namenda XR and the twice daily therapy, and, in doing so, to "avoid competing against lower-cost generics based on the merits of their redesigned drug." *Id.* Nothing within the Second Circuit decision forecloses Plaintiffs' claims.

In fact, the decision does quite the opposite. The Second Circuit said, in no uncertain terms, that the illegal hard switch began well before the date Forest intended to withdraw Namenda IR. According to the Second Circuit:

> The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a "standstill" during the litigation proceedings described below. Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.

Namenda II, 787 F.3d at 654. Having defined the hard switch in that way, the Second Circuit further undermines Defendants' arguments, since it makes clear that it believed conduct that was substantially likely to be found illegal began before the entry of the injunction — like Judge Sweet said in his opinion.

Next, Defendants argue that Forest's announcement of the withdrawal and its petition to the Centers for Medicare & Medicaid Services was commercial speech, protected under the First Amendment. (Forest's Br. at 20-24.) However, the First Amendment does not provide protection for conduct that violates a federal statute. *See, e.g., Cal. Moto Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972); *see also FTC v. Sup. Crt. Trial Lawyers Ass'n.*, 493 U.S. 411, 430-32 (1990). And in this very context — an attempted hard-switch by a pharmaceutical company — courts have expressly held that raising the First Amendment "as a talisman" does not protect an otherwise anticompetitive "hard switch" from antitrust scrutiny. *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 424 (D. Del. 2006). As in that case, the fact that Defendants' conduct was truthful commercial speech is no defense if it is found to be anticompetitive.

Not one of the cases cited by Defendants to support their commercial speech argument says otherwise. Defendants read these cases to say that a company with monopoly power may introduce and promote a new product without violating federal antitrust laws, but they all center on the distribution of promotional materials and advertisements — tactics of the so called "soft switch," which has been found not to violate federal antitrust laws. *See, e.g., Sorrell*, 131 S. Ct. at 2659; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 496 (1996); *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1129 (7th Cir. 1893). In none of those cases did a company announce its intention to withdraw an older product to force consumers to adopt a new one, so the coercive element that is at issue here is absent in all of these cases. Because the

underlying conduct in these cases did not violate the federal antitrust laws — unlike the alleged conduct at hand — a First Amendment defense may be possible.

Finally, Defendants argue that Plaintiffs lack standing. According to Defendants, Plaintiffs cannot establish an injury-in-fact, since (1) the hard switch never occurred, (2) Namenda XR was priced below Namenda IR prior to generic entry, and (3) the price of generic Namenda IR was less than 10% of the July 2015 Namenda IR price after generic entry. (Forest Br. at 31.)

For the reasons stated above, Plaintiffs have alleged an injury, because they allege that they were forced to pay for certain patients' memantine treatment at brand-name prices because these patients switched to Namenda XR *prior* to the entry of the injunction. Assuming Plaintiffs can ultimately prove that these patients switched to Namenda XR because of the announced withdrawal of Namenda IR, it is entirely irrelevant that the hard switch never occurred and that Namenda XR was priced below Namenda IR prior to the injunction. Plaintiffs' injury comes from having to pay for Namenda XR *after* generic entry — when absent Defendants' anticompetitive conduct, their patients' prescriptions would have been filled by a far cheaper generic (which, as Defendants state, was available for less than 10% of the July Namenda IR price).

Plaintiffs' claims are well-pleaded.

III. Plaintiffs Have Stated a Claim Based on the Settlement Agreements

The Direct Purchaser Plaintiff also claims that Forest and the Generic Defendants colluded to delay entry of generic Namenda IR into the memantine-market, in violation of Section 1 of the Sherman Antitrust Act. According to Plaintiff, Forest settled patent litigation suits with each of the Generic Defendants, and these settlements — by design — delayed generic entry.

Defendants do not deny the existence of the settlements; such settlements are a common means through which parties resolve litigation initiated by a generic manufacturer's Paragraph IV certification. Forest and the Generic Defendants argue, however, that the Plaintiffs have not pleaded facts suggesting that the settlement agreements signed by Forest and the Generic Defendants (as well as Forest and two unnamed defendants) were anticompetitive. Specifically, they argue that Plaintiffs have not alleged that Forest made large and unjustified reverse payments to the Generic Defendants, as required by *FTC v. Actavis, Inc.*, —— U.S. ——, 133 S. Ct. 2223 (2013), or that Plaintiffs suffered damages as a result of the agreements, because the agreements did not delay generic entry past the expiration of Namenda IR's patent and regulatory exclusivity period.

Neither of these arguments warrants dismissal. Plaintiffs' Section 1 claims may not pass muster at some later stage of this litigation. However, at this juncture, Defendants have not shown that Plaintiffs' claims fail under *FTC v. Actavis.* Accordingly, Defendants' motions to dismiss Plaintiffs' Section 1 claims are denied.

A. Legal Standard

The relevant legal standards for deciding whether patent litigation settlement agreements are anticompetitive were set forth in *FTC v. Actavis*. In *Actavis*, the Federal Trade Commission sued a manufacturer of a brand-name drug, Solvay Pharmaceuticals, and two generic competitors, Actavis and Paddock, for entering into "reverse payment" settlement agreements like those at issue in this case. 133 S. Ct. at 2224–25. Pursuant to those settlements, the generic manufactures agreed to delay bringing to market generic versions of Solvay's brand name product, Androgel, and to promote it to doctors in exchange for a "reverse payment" — that is, a payment from the brand manufactures (the patent holder) to the generic manufactures (the

alleged patent infringers) — of several millions of dollars. *Id.* at 2225. According to the FTC, these settlements were anticompetitive because they resulted in the generic manufacturers abandoning their patent challenges and delayed generic competition in exchange for a share of the brand name drug manufacturer's monopoly profits. *Id.* The district court dismissed the case and the Eleventh Circuit affirmed, holding that a reverse payment agreement was generally "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 2227 (quoting *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012)).

The Supreme Court reversed. It held that though a settlement agreement containing a reverse payment is not presumptively unlawful, a reverse payment, "where large and unjustified," can result in anticompetitive harm when a patent holder seeks to "exclude products or processes that do not actually infringe" the patent by paying the alleged generic manufacturer to stay out of the patent holder's market. *Id.* at 2231, 2233, 2237.

The Court was careful to say that patent holders could still lawfully settle with an alleged infringer — for example, "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 2237. However, the Court said courts must determine the anticompetitive effect of such settlements "by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Id.* at 2231.

To trigger antitrust concern under *Actavis*, a settlement term must be "(1) a 'payment' that is (2) made in 'reverse' — that is, from the patent holder to the alleged infringer — and is (3) 'large,' and (4) 'unexplained.' *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 RA,

2015 WL 5610752, at *11 (S.D.N.Y. Sept. 22, 2015) (quoting *Actavis*, 133 S. Ct. at 2237). Because the "existence and degree of any anticompetitive effects" may vary depending on the particular settlement and the relevant industry," plaintiffs must show that the settlements are anticompetitive under the rule of reason analysis applied to other types of antitrust claims. *Id.* (quoting *Actavis*, 133 S. Ct. at 2237). In this Circuit, that involves three steps:

> First, the plaintiff bears the initial burden of showing that the defendant's conduct had an actual adverse effect on competition as a whole in the relevant market. If plaintiff satisfies this burden, the burden then shifts to [the] defendant to offer evidence that its conduct had pro-competitive effects. If [the] defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives.

Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 104 (2d Cir. 2010); *see also In re Actos*, 2015 WL 5610752, at *11.

B. Alleged Unlawful Reverse Payments

In accordance with these principles, the Court must assess whether Plaintiffs have plausibly pleaded a reverse payment with an anticompetitive effect. The settlements agreements in this case differ from those in *Actavis* in that the main "consideration" paid to the Generic Defendants was not a large cash payment — rather, it was an agreement to license Forest's patent. Contemporaneously with the execution of each of the ANDA settlement agreements, Forest and the individual Generic Defendants entered into licensing agreements granting the individual Generic Defendants licenses to manufacture a generic version of Namenda IR "[three] calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity." (*See, e.g.,* Decl. of Kristen O'Shaughnessy ("O'Shaughnessy Decl.") Exh. 1 at FRX-AT-00000236.) Pursuant to these agreements, the Generic Defendants could begin marketing generic Namenda IR in July 2015, rather than October 2015 when Forest's patent exclusivity period ended.

Given this fact, Defendants argue that the settlement agreements do not contain any provision that meets the Court's definition of an impermissible reverse payment, much less a reverse payment that is large or unexplained. According to Defendants, the settlement agreements contain only two types of "consideration" — (1) payments to cover the Generic Defendants' litigation costs and attorney fees and other compensation for promoting Namenda IR; and (2) early-entry licenses — both of which were expressly permitted by *Actavis*. (See, e.g., Mem. of Law ISO Generic Defs.' Mot. to Dismiss Indirect Purchaser's Class Action Compl. (Dkt No. 81) ("Generic Defs.' Br.") at 13; Forest Br. at 36-37.)

1. Litigation Costs and Attorney Fees

The licensing agreements executed contemporaneously with the settlement agreements included provisions by which Forest made payments to the individual Generic Defendants to defray a portion of their attorney fees and other litigation costs that they had already expended.[6] These payments were not particularly large, according to the licensing agreements, because the litigation had not progressed very far and very little money had already been spent. (*Id.*). (*See* O'Shaughnessy Decl. Exh. 1 at FRX-AT-00000238; Exh. 5 at § 2.5; Exh. 6 at § 2.5.)

In *Actavis*, the Court did not say what constitutes a "large" or "unjustified" reverse payment, but it instructed courts (1) to compare a payment to the payor's future litigation costs as a measure of scale to determine if it was "large," and (2) to consider whether a payment "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services" to determine if it was justified. *Actavis*, 133 S. Ct 2237.

These intrinsically fact-based determinations cannot be made on a pre-answer motion to dismiss. Discovery is needed to reveal whether the payments Forest made to the Generic

[6] These payments were contingent upon review by and no objection from the Federal Trade Commission. (O'Shaughnessy Decl. Exh. 1 at FRX-AT-00000239.)

Defendants were actually commensurate with the legal fees they expected to pay over the course of the ANDA patent litigation, or constituted reasonable compensation for promoting brand-name Namenda IR to doctors and patients. Plaintiffs have alleged that these payments exceeded reasonable costs and compensation; without evidence related to what the Generic Defendants had already paid in legal fees and what they reasonably could be expected to continue paying if they had continued to litigate the patent infringement actions, the Court cannot say, as a matter of law, that the payments were not large and unjustified.

Forest draws the Court's attention to an FTC settlement in which the FTC blessed any payments to potential generic manufacturers for attorneys' fees and other litigation costs made by a certain pharmaceutical company in the course of settling ANDA patent litigation as long as such payments were under $7 million. *See* FTC Press Release, FTC Settlement of Cephalon Pay for Delay (May 28, 2015), https://www.ftc.gov/newsevents/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill; *FTC v. Cephalon Inc.*, No. 08-cv-2141 (E.D. Pa. June 17, 2015), ECF Dkt. No. 405 (compensation for litigation costs up to $7 million did not constitute reverse payment). But this safe harbor only applied to future settlement agreements signed by the defendant in that specific case. It did not signify that the FTC believes that such a safe harbor exists generally as to all companies entering into such agreements.

2. Early-Entry Licenses

The other "consideration" present in the settlement agreements are early-entry licenses allowing the Generic Defendants to begin marketing generic Namenda IR before the end of Forest's patent exclusivity period. Though these payments appear to be proper under *Actavis*, the legality of these terms is better decided on a motion for summary judgment, after discovery has taken place.

At the outset, it is not clear whether such early-entry settlement terms are "reverse payments" within the meaning of *Actavis*. In *Actavis*, the Court appeared to sanction early-entry settlement terms as an alternative means of settling patent litigation, and noted that a "settlement on terms permitting the patent challenger to enter the market before the patent expires would . . . bring about competition . . . to the consumer's benefit." *Id.* at 2237. However, the settlement agreements at issue in *Actavis* did not involve early-entry settlement terms, and thus the Court did not expressly hold that settlements that merely provide for the early-entry of a generic do not trigger antitrust scrutiny, *see* 133 S. Ct. at 2234.

Several courts have addressed that issue head-on. In one such recent case, *In re Actos*, 2015 WL 5610752, at *13, my colleague Judge Abrams considered whether such early-entry terms in settlement agreements signed by the manufacturer of a brand name diabetes drug and various generic competitors were anticompetitive reverse payments. As here, the settlement agreements provided for early entry of generics into the market — in some cases, allowing generic entry four years before the expiration of the patent. *Id.* After noting that settlement terms providing for "a compromise date of generic entry" were "the very type of settlement sanctioned by the *Actavis* Court," she held that the agreements did not trigger antitrust scrutiny. *See Id.* The court's holding was consistent with courts outside this circuit that have also held that early-entry license settlements terms were procompetitive and thus do not run afoul of *Actavis*. *See, e.g., FTC v. AbbVie*, —— F.Supp.3d, —— 2015 WL 2114380 (E.D. Pa. May 6, 2015); *In re Niaspan*, 42 F.Supp.3d at 751–52. This case law, in conjunction with the *dicta* in *Actavis*, suggests that early-entry terms are not reverse payments subject to antitrust scrutiny.

Nonetheless, this Court also cannot determine as a matter of law on a pre-answer motion to dismiss that these terms are *not* anticompetitive. *In re Actos*, like *Actavis*, was a case that

centered solely on ANDA settlement agreements; there were no allegations that the brand-name defendants engaged in an allegedly anticompetitive product-hop. Here, by comparison, the settlement agreements allegedly had a second anticompetitive effect, apart from foreclosing a challenge to the viability of Forest's patent: allowing the Company to complete its anticompetitive "hard switch" strategy. According to Plaintiffs, the terms of the licenses were intentionally designed to keep competitors out of the market *until* the Company had successfully forced Namenda IR consumers to switch to Namenda XR and thus extended their monopoly and resulted in them overpaying for memantine-treatment. The potential anticompetitive effects of Forest's actions — though allowing for the Generic Defendants' early entry into the memantine-drug market — are idiosyncratic enough to distinguish the effects of the early-entry licenses granted to the Generic Defendants from those at issue in *Actavis* and *In re Actos*, and to require discovery to determine whether the early-entry licenses were in fact anticompetitive.

Defendants are correct that, viewed in isolation, the settlement terms do not appear anticompetitive. The settlements terms permitted generic entry three months *before* Forest's patent exclusivity period expired, which, in effect, expedited the entry of generic competition into the market for memantine therapy. Plaintiffs argue, only summarily, that the early-settlement terms delayed generic entry. Presumably, Plaintiffs mean that absent the agreements, the Generic Defendants would have continued litigating the validity of Forest's Namenda IR patent in 2009 and 2010, shown Forest's patent to be invalid, and entered the memantine market long before June 2014. However, they have alleged no fact to suggest that Forest's patent was invalid or that the Generic Defendants were likely to be successful in arguing that their products did not infringe Forest's patent, and thus that the Generic Defendants would have been able to enter the memantine market any earlier than they eventually did, absent the settlement

agreements. To survive a motion for summary judgment, Plaintiffs will have to substantiate these allegations with evidence suggesting that the settlement agreements did, in fact, delay generic entry and that the delay had the effect of allowing Forest to complete the hard switch.

C. The Direct Purchaser Plaintiff's Claims Are Timely

Finally, Defendants argue that the Direct Purchaser Plaintiff's settlement agreement claims are time-barred because its complaint was filed more than five years after the last settlement agreement was executed. That is not correct.

The alleged wrong suffered by Plaintiffs is the payment of artificially high prices for memantine-treatment — something that occurs every time Plaintiffs have to pay for a patient's brand-name Namenda XR or Namenda IR medication when, absent Forest's or Forest and the Generic Defendants' allegedly anticompetitive conduct, they would have instead paid far less for a generic Namenda IR product. The wrong complained of is not the execution of the settlement agreements — acts that did not themselves cause any injury to Plaintiffs until the resulting overcharge hit them in their pocketbooks. It is true that those acts laid the foundation for the pocketbook injury Plaintiffs ultimately suffered; but the actual injury was worked by the overcharge itself, which, according to Plaintiffs, occurs on an ongoing basis. As the Second Circuit explained, a "purchaser's claim cannot accrue until it actually pays the overcharge," so a "purchaser suing a monopolist for overcharges paid within the previous four years may satisfy the conduct prerequisite to recovery by pointing to anticompetitive actions taken before the limitations period." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 295-96 (2d Cir. 1979).

The fact that those foundational acts took place more than four years before the Direct Purchaser Plaintiff filed its complaint here is irrelevant. The Direct Purchaser Plaintiff may assert

claims for damages it incurred up to four years prior to the filing of its complaints — that is, September 22, 2011.

The Direct Purchase Plaintiff's claim is not time-barred.

IV. Plaintiffs' Overarching Scheme Claim is Duplicative and Should be Dismissed

Plaintiffs also allege that Forest's product hop and its agreements with the Generic Defendants were part of "an overarching scheme to unlawfully maintain Defendants' monopoly in the market for memantine hydrochloride." (*See* DPP Forest Br. at 40.) Plaintiffs have failed to explain why this claim is not duplicative of their claims related to the product hop and the settlement agreements, and have cited no cases suggesting that they may proceed with three sets of claims. The claim is therefore dismissed.

V. The Indirect Purchaser Plaintiff's State Law Claims Are Stayed and Forest's Motion to Dismiss Them Is Denied Without Prejudice

The Indirect Purchaser Plaintiff claims that Defendants violated numerous states' antitrust and unfair competition statutes. In the interest of judicial economy and docket management, the Court declines to dismiss these claims until the Direct Purchaser Plaintiff's federal antitrust claims have been resolved. If the Direct Purchaser Plaintiff's federal claims are ultimately dismissed, this Court will determine whether the Indirect Purchaser Plaintiff's state claims have merit. There is no reason for this Court to spend its time delving into the arcana of myriad state antitrust and unfair business practices laws before the factual record in this case is developed and the federal claims are resolved one way or another.

Accordingly, Defendants' motions to dismiss the state claims are denied without prejudice to renewal after the federal claims have been resolved; the Indirect Purchaser Plaintiff's claims are severed and placed on the Court's suspense calendar.

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss the claims are denied. The Clerk of the Court is directed to remove Docket Numbers 80 and 83 from the Court's list of pending motions in Case Number 15-cv-6549 and Docket Number 55 from the Court's list of pending motions in Case Number 15-cv-7488.

Dated: September 13, 2016

U.S.D.J.

BY ECF TO ALL COUNSEL